K041326

JUL 27 2004

510(k) Summary for the MedCommons Open Radiology™ Gateway

This 510(k) summary of safety and effectiveness information complies with 21 CFR 807.92.

Submittal information:

Manufacturer:
MedCommons, Inc.
52 Marshall Street
Watertown, MA 02472

Contact person:
Adrian Gropper, M.D.
Chief Medical Officer
MedCommons, Inc.
52 Marshall Street
Watertown, MA 02472

(617) 571-3857

Device name and classification

Proprietary Name:	MedCommons Open Radiology™ Gateway
Classification Name:	Picture Archiving and Communications System
Classification Panel:	Radiology
CFR Section:	21 CFR 892.2050
Class:	II
Product Code:	LLZ

Substantial Equivalence

The MedCommons Open Radiology™ Gateway is substantially equivalent to the eFilm Workstation, which was cleared in 510(k)'s K020995 and K012211.

Device Description

MedCommons Open Radiology™ Gateway (MedCommons Gateway™) is a component of a Picture Archiving and Communications System (PACS). MedCommons Gateway™ is a software application that provides image viewing and manipulation in a diagnostic imaging setting. The functions of this application are applied to medical images that are acquired and stored on an image server in DICOM and/or other proprietary formats. MedCommons Gateway™ can also transfer DICOM 3.0 images over a medical imaging network, as well as export images to applications in JPEG and/or proprietary formats.

Intended Use

MedCommons Open Radiology™ Gateway (MedCommons Gateway™ is a software application for viewing medical images. Typical MedCommons Gateway™ users are healthcare professionals, such as, clinicians, radiologists, and technologists.

MedCommons Gateway™ receives, communicates, and displays digital images and data from various types of imaging and image processing system, such CT, MR, US, RF units, computed and direct radiographic devices, scanners, imaging gateways and image processing sources). MedCommons Gateway™ can be integrated with an institution's HIS or RIS, linking or transferring images and data into electronic patient records.

Comparison to the predicate device

The MedCommons Open Radiology™ Gateway and the eFilm Workstation are both software applications intended for viewing medical images stored in PACS systems. They have similar features and are substantially equivalent in safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 27 2004

MedCommons, Inc.
% Mr. Chas Burr
Consultant
SoftwareCPR, Inc.
11 Mystic Avenue
WINCHESTER MA 01890-2920

Re: K041326
Trade/Device Name: MedCommons Open Radiology™ Gateway
Regulatory Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: May 17, 2004
Received: May 18, 2004

Dear Mr. Burr:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K041326

Indications for Use

510(k) Number (if known): _____

Device Name: _ MedCommons Open Radiology™ Gateway _____

Indications for Use:

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Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K041326